



Submission to the House of Commons Health Committee (HESA)

Ensuring increased benefits to the public resulting from federally funded health research, with the goals of lowering drug costs and increasing access to medicines, both in Canada and globally

October 2018

Introduction

FINDⁱ and TB Allianceⁱⁱ are pleased to submit the following brief for consideration by the House of Commons Standing Committee on Health. Our submission describes the important role played by innovative research and product development initiatives in reducing costs and improving access to diagnostics, drugs, and vaccines in Canada and globally. We will share recommendations about how Canada can maximize the impact of the funding it invests.

Innovations in Health Financing

In the early 2000s, in response to the global focus on meeting the millennium development goals, several exceptionally successful health initiatives were launched. These include GAVI, the Vaccine Alliance, the Global Fund to Fight AIDS, TB and Malaria, and UNITAID. All shared the goal of supporting better access to health services and better health outcomes in lower and middle income countries (LMIC). The positive impact of these innovations in saving lives and improving the global economy has been well documented.ⁱⁱⁱ Canada was a strong supporter of these initiatives and hosted the replenishment conference for the Global Fund in September, 2016. This was the largest ever resource mobilization in health with USD12.9bn pledged, thanks in no small part to strong leadership from Canada.

At the same time as these innovations in health financing were launched, global leaders in health and development came together to analyze the conditions that perpetuate the discrepancies between developed and developing countries in terms of their access to health services and commodities. The cost of drugs, vaccines, and diagnostics was initially a limiting factor in equitable health around the world; but by-and-large, the cost factor was addressed by the creation of financing mechanisms such as the Global Fund. Market failure, however, was identified as an enduring obstacle to improving global health.

Market Failure and Its Impact on R&D

In TB care, the drug manufacturing industry is not motivated to invest in developing a product for a disease which has limited sales potential in rich countries. Consequently, we are still using drugs that were developed 50 years ago and a vaccine that was developed in 1921, which has negligible impact in adults and only limited efficacy in children.^{iv}

Market failure exists for product development that targets any disease that has a limited impact in developed countries. For example, research on vaccines, vector control, drugs, and diagnostics for malaria is a priority for the US military as a duty to their troops, but otherwise there is limited interest among private sector investors and manufacturers because the products developed will only be sold in regions that have limited purchasing power.

Product Development Partnership Model

To address these market failures and ensure that health commodities were developed to address the global health crisis, the product development partnership (PDP) model was created. A PDP is a non-profit organization that develops innovative and affordable medicines, diagnostics and vaccines for populations affected by poverty-related and neglected tropical diseases. PDPs focus on unmet patient needs by designing products for use in low- and middle-income countries with high disease burdens.^v They bring together industry, academia, governments, and health professionals in a unique way that reduces the time needed to launch a product and ensures that costs are not skewed by impractical profit retention. PDPs focus on developing drugs, diagnostics, and vaccines in a wide range of diseases including HIV, TB, malaria, anti-microbial resistance (AMR), and several neglected diseases such as Dengue and Ebola. The role of PDPs in addressing AMR was specifically noted in the October 4th, 2018, Declaration from the G20 Meeting of Health Ministers, Mar del Plata, Argentina^{vi}

Access: A Complex Issue in Need of a Balanced Approach

In the PDP model, given that the products are generated with public funds, the benefits are meant to be enjoyed as a global public good which will, at the same time, safeguard a sufficient profit for industry to ensure that quality products are produced and distributed globally. PDPs follow a set of principles that addresses the complex issues of intellectual property rights while ensuring access to innovations where needed.

TB Alliance, for example, follows the “AAA” Mandate – Affordable, Available, and Adoptable. This means that they negotiate agreements with industry partners that call for joint intellectual property (IP) rights and limit exclusive licenses in high-income countries. This approach ensures healthy competition in all other countries by granting royalty-free, non-exclusive licenses to at least two different companies. Industry partners are also expected to make their product affordable (defined as cost plus a reasonable profit to ensure that the product is made available on a sustainable basis).

All PDPs are also very active in working with WHO and other stringent regulatory authorities to build the evidence needed to obtain product approval, as well as the guidance needed by local governments to introduce a new diagnostic, drug, or vaccine into a health system. PDPs work closely with local health authorities to support them to quickly approve and implement innovations.

Why and How PDPs Benefit Canada

Canada has invested in PDPs including through the International AIDS Vaccine Initiative (IAVI) and the International Partnership for Microbicides (IPM). Both were funded by CIDA as part of

Canada's commitment to address HIV, and involved substantial engagement by Canadian researchers and government agencies. While funding for these PDPs stopped in 2010, Canada can still take credit for the Dipivefrin ring, a groundbreaking HIV prevention technology.^{vii}

While the primary focus of PDPs is to address the global health crisis, it is important to note that many of the innovations developed by PDPs are being used in Canada. The GeneXpert TB assay test, which was developed with support of FIND, is an example. This tool is being used throughout Canada because it is able to diagnose TB in two hours and replaces the decades-old microscopy method, which takes two weeks. The GeneXpert test is also able to identify drug resistant strains of TB to ensure better treatment regimes.

Canada and Inuit leaders have committed to eliminating TB in Inuit Nunangat by 2030. Recently, FIND and TB Alliance briefed the Minister of Indigenous services, Jane Philpott, and her staff about new TB diagnostics tools and drugs that are being developed by our organizations that will have an impact on meeting this goal. The drug regimens being developed by TB Alliance will also have an impact on treating latent TB throughout the country.

PDPs—Low Cost of Engagement and High Return on Investment

Investments already made to global health initiatives such as the Global Fund are more effectively used if better diagnosis is available and shorter treatment regimens can be rolled out. The return on investment in Global Fund spending will significantly increase from a relatively modest investment in R&D.

Unlike other R&D funding initiatives, PDPs offer a low threshold of entry and negligible ongoing engagement costs. The PDP mechanism offers an opportunity that minimizes risks otherwise taken by a single donor by sharing the investment burden: oversight, evaluation, and fiscal monitoring with other governments and foundations. The PDP funders group is currently chaired by the United Kingdom. A full list of partners is shown in Annex A.

Recommendations

- Engage with like-minded countries to support research and product develop through PDPs and accelerate access to affordable diagnostics, drugs, and vaccines that will have a benefit within Canada and globally.
- Require recipients of R&D federal funding to include a clearly defined "access plan" for how the end product will be made available in Canada and globally.

AnnexA. Current Members of the PDP Funders Group

Members include government agencies, private foundations, and other organizations:

- UK Department for International Development (Chair)
- Bill & Melinda Gates Foundation
- Department for Foreign Affairs and Trade, Australia
- European Developing Countries Clinical Trials Partnership (EDCTP)
- Federal Ministry of Education and Research (BMBF), Germany
- Global Health Innovative Technology Fund
- Irish AID
- KFW Development Bank, Germany
- Ministry of Foreign Affairs, Netherlands
- Norwegian Agency for International Development Cooperation
- Swiss Agency for Development and Cooperation
- UNITAID
- Wellcome Trust
- The Global Fund (joined as of Oct 2018)

ⁱ FIND was established in 2003 as an international non-profit organization. It is dedicated to accelerating the development, evaluation and use of high-quality, affordable diagnostic tests for poverty-related diseases, including tuberculosis, malaria, HIV and AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, febrile illnesses and infectious diseases with outbreak potential, such as Ebola. Over the last decade, FIND has partnered in the delivery of 22 new diagnostic tools, including eight for tuberculosis, and has created an enabling environment for numerous others through the provision of specimen banks, reagent development and better market visibility. FIND also supports better access to new diagnostics through implementation, quality assurance and lab strengthening work. FIND has over 200 partners globally, including research institutes and laboratories, health ministries and national disease control programs, commercial partners, clinical trial sites, and bilateral and multilateral organizations (especially WHO).

ⁱⁱ TB Alliance is a not-for-profit organization dedicated to the discovery and development of better, faster acting and affordable drugs for tuberculosis (TB). Before TB Alliance was established in 2000, there were no new TB drugs in clinical development. Today, TB Alliance's has successfully launched childhood TB products already reaching patients in over 60 countries and is coordinating the largest ever portfolio of novel TB drugs and regimens ranging from early drug candidates to regimens ready to introduce in the coming years—more than 30 active projects in all. The goal of these programs is to introduce new treatments that will significantly impact the TB pandemic.

ⁱⁱⁱ The Global Fund Results Report, 2018, The Global Fund, Geneva, August 2018

https://www.theglobalfund.org/media/7741/corporate_2018resultsreport_report_en.pdf

^{iv} Accelerating Development of Essential New Tools to End TB https://www.finddx.org/wp-content/uploads/2018/06/Essentialnew-tools-infosheet_19JUN18.pdf

Qu'est-ce qu'un DEU? Medicines for Malaria Initiative. Geneva, 2017

<https://www.mmv.org/sites/default/files/content/infographic/files/ThePDP.pdf>

^{vi} Declaration of G20 Meeting of Health Ministers October 4th, 2018, Mar del Plata, Argentina. P3.

https://g20.org/sites/default/files/health_ministers_declaration.pdf

Pour en savoir davantage, consultez : <https://www.ipmglobal.org/our-work/our-products/dapivirine-ring/phase-iii-results>